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# DEVELOPMENT OF A HIGH DENSITY PERCUTANEOUS CONNECTOR SYSTEM

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## Abstract

This report summarizes activity over the period from October 15, 1997 through January 15, 1998 on NIH Contract N01-DC-7-2103, "Development of a High Density Percutaneous Connector System". During this period work was completed on three implants at HMRI and the next HMRI work was defined; cable design revisions were completed to be included in the HMRI work during the 4th quarter; work has progressed toward obtaining a ceramic frit from IJ Research; an investigation into other materials for use in the pin matrix has started; initial steps have been taken to develop a suitable quick disconnect; the reliability of the anisotropic elastomer has been discussed with a focus on failure mechanisms and alternatives and improved skin growth has become a significant focus with connections to UWEB and Pacific NW National Laboratories (PNL).

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## I. Background and Review of Contract Requirements

This report summarizes activity from July 15 through October 15, 1997, on NIH Contract N01-DC-7-2103, "Development of a High Density Percutaneous Connector System". Over the course of this contract, a high density, planar, low profile connector system is being developed that incorporates pad grid array technology. This technology has unique advantages as applied to a percutaneous interconnect system. In particular the connector system will be low in profile, easy to clean, sealed against ingress of contaminants, offer low mechanical resistance to mating and demating and provide a very high number of contacts in a small diameter. The connector system will be implanted in a suitable animal model and the appropriate electrical, mechanical, and biocompatible properties of the system will be assessed. The specific technical requirements of this connector system as detailed in the contract are explained below:

- The connector will incorporate a pedestal that can be attached to the skull in a mechanically stable manner. The pedestal will be designed to accept a replaceable connector assembly. All materials of the pedestal in contact with tissue will be biocompatible and the profile of the pedestal will be low enough to minimize any physical trauma during mating and demating of the connector or due to normal physical activities.

- The connector assembly will be high-density with at least 70 contacts. The electrical isolation between the contacts or between the contacts and the body should withstand at least 18 volts without breakdown. The connector contacts when mated should be capable of passing up to 20 mA of current with less than a 1.0 volt drop across the connection. A simple method of mating and demating the upper and lower surfaces of the connector should be provided. In addition, a convenient means to attach electrical leads to the connector is needed.

- The connector will be designed from materials that are durable and can withstand the physical abuse from normal activities of daily living. The interface between the connector and the skin must be such that the passage of microorganisms into the body and fluid drainage out of the body is prevented.

- In earlier studies connectors had 5 separate loops of insulated wire, each 2 inches long. Because of wire breakage observed during these studies it is necessary to make a more durable and a more realistic part. Future connectors will have only one flat "cable" 1 to 1.5 inches long with 10 Pt/Ir wires, each 10 mils in diameter, coated with Parylene and Silicone. The ends of the wires are welded so as to make 5 "loops" and the ends will be coated with Silicone. An 18 volt bias will be maintained on the connector contacts and insulated wires relative to an implanted platinum wire connected to one of the unused contacts. The leakage current of the wires will be monitored and if more than 10 nanoamperes of current is detected, the source of the leakage will be identified and corrected.

- Performance of the connector system will be tested in a suitable animal model. After six months of implantation, the connector assembly will be explanted and gross and

microscopic examinations will be performed to study the attachment of the pedestal to the skull, the attachment of the skin and soft tissue surrounding the pedestal to the pedestal wall and the reaction of adjacent tissue to the implanted device.

- Finally, design changes and improvements, if needed, will be recommended. A set of connectors will be fabricated and sent to the NIH for implantation into primates and eventually humans as part of their ongoing research.

## II. HMRI Work Completed

Dummy connectors have been fabricated and provided to HMRI for implant in cats. The purpose is to evaluate skin growth to three case surfaces: plain-machined surface, grooved surface and a Tantalum sponge surface. The dummy connectors have no subcutaneous cable, but they do have the shaped Ti bead base for osseointegration. Two cats were sacrificed in mid-December, the third (sponge Ta case) in January. Preliminary histology results are available for the first two cases and are included in Appendix I with a summary presented here.

The machined surface did not have good bone or skin integration showing epithelial downgrowth and marsupialization (verbal communication not in Appendix I). The ossiointegration was poor, occurring only near the Ti screws holding the pedestal to the skull. There were active inflammatory processes in the dermis, the subcutaneous tissue and extending several hundred micrometers under the Ti pedestal.

The grooved surface had both good bone and skin integration. There was no evidence of epithelial downgrowth or infection of skin or subcutaneous tissue indicating good integration of the skin to the Ti wall. The average ossiointegration based on three sections was 66.2% (measured linearly) with no inflammation of the bone tissue.

The preliminary histology has not been completed on the third case with Ta sponge around the Ti dummy connector. However, there were difficulties with the surgery and the skin apparently never healed properly possibly invalidating this work as a skin experiment. If good results are unexpectedly obtained they will certainly be valid. However, failure would not invalidate the Ti sponge as a surface and any infection could possibly invalidate the ossiointegration. The sponge was 1000 micrometers thick (40 mils). Even if skin were to successfully grow into the sponge, it would likely not grow the full 1000 micrometers leaving a path through the sponge for infection. Future sponge work (Ta and Ti sponges have both been considered for follow-on though they are not being pursued at present) should be with material less than 250 micrometers, probably near 25 to 50 micrometers thick.

## III. Change of Cable Geometry

Flat ribbon cable was constructed consisting of five loops of Parylene coated one mil Pt/Ir wire. These were laid out parallel and coated with a thin layer of Silicone. After this Silicone set, the cable was turned over and a second thin Silicone coat was applied to the bottom of the cable to provide a complete seal. Reinforcement fibers were included in the cable and are to be attached inside the connector. The wires will make at least a

90 degree turn inside the connector. The wire loops will extend one inch outside the connector body.

## IV. Status of Fritting Experiment

IJ Research is having Cabal-12 preforms made for three dummy connectors to be fabricated by mid-March. This is a reduction from the original plans of ten – five with Pt/Ir wire and five with Au wire. Two of the three dummys will have Pt/Ir pins and one will have Ta pins to look at strains induced in the ceramic during cooling. The Au wire was excluded because of unacceptable thermal expansion differences. The last quarterly report stated that we would use a full 64 pins in the experiment, but less is known about the process than was then thought and the present work is limited to the original 12 pins.

Follow-on work is expected to move to the full >70 pin connector instead of the 64 pins now in use because of the cost of tooling at each step. This will require modification of the entire connector to accommodate the additional pins. Therefore, if the present work is successful, follow-on work will probably be done with 12 pin dummys until experience and confidence justify moving to the full connector.

Investigation into glass and ceramic alternatives to Cabal-12 continues, but there are not acceptable alternatives at this time.

## IV. Investigation Into Other Pin Matrix Materials

The present connectors have pins imbedded in a matrix of Alumna and EpoTek 301 epoxy. EpoTek 301 is a medical Class VI material and is acceptable for implant. However, it is exposed to moisture on at least one side (water from body fluids through Silicone) and it is expected that the epoxy will degrade unacceptably in much less than the objective ten years. The frit experiment (using Cabal-12 at present) is intended to find an acceptable long-term pin matrix material. However, this process, even if successful, would be costly in time and money. For that reason a search for higher cross-linked materials with more stable bonds has been undertaken. There are definitely polymers that would have more desirable properties than EpoTek 301 and which would be much more manufacturable than any glass or ceramic process. The cost in time and money for this project is almost negligible compared to the glass and ceramic work.

To look for alternatives for the Cabal-12 experiment we are looking at epoxies, Silicones and Acrylics with highly cross-linked, more stable bonds than the EpoTek 301 epoxy presently used. This is easily done in house since PI Medical routinely uses these materials. The method to be used is to drill ¼ inch holes in two pieces of 200 mil thick Ti. The two pieces of Ti will be similar with each hole filled with a different material to be studied. Each material will have two Pt/Ir wires imbedded approximately 100 mils apart for leakage testing. The test pieces will be placed in Ringers solution, one held at body temperature, the other at elevated temperature for an accelerated life test. It is expected that the experiment would continue for at least six months with periodic examination.

## V. Connection of Top and Bottom Sections

The present method of using two screws to connect the top and bottom sections of the connector is cumbersome at best. PI Medical is presently working with Phoenix Interconnect in Santa Ana, CA. Phoenix Interconnect has developed a quick disconnect mechanism for military applications; their connector is larger than that being developed under this contract. During February it is expected that Phoenix Interconnect will make recommendations as to how their method could be applied to the percutaneous connector (concepts only). Design will follow with first fabrication in March or early April.

## VI. Reliability of the Anisotropic Material from Shin-Etsu

Concern has often been expressed about the reliability of the anisotropic elastomer obtained from Shin-Etsu. The material in use is twenty-year-old technology with failure mechanisms not fully understood. However, it is known that failures occur at the time of insertion and during use days, weeks or months after the elastomer is in place. This is not acceptable. Shin-Etsu has newer materials that may be useful and other alternatives are being investigated.

The Shin-Etsu material being used is type MAS. This has randomly placed "chunks" of Au plated metal of random size. The newer GBM material has regularly spaced wires (Au plated Brass) at 10 mils by 4 mils seems to work well on the present connector with 17 mil pins and 30 mil pitch. It does not work reliably on the 13 mil pin. The material is a marked improvement over the MAS material and will be used. However, even the GBM material is not an acceptable long-term solution. Reliability, though improved, may not be acceptable and small pin size and spacing would not be possible. For these reasons other commercial materials and inexpensive internal methods are being looked into as alternatives.

## VII. Skin Growth

As reported in the HMRI work, potentially useful skin growth occurred in only one of three implants during the quarter. Of the three, one failure may have been the result of surgical difficulties. This remains a major area of concern and alternatives to grooved Ti are being sought. Alternatives are covered in the section on the Fourth Quarter Activities.

## VIII. Activities for the Fourth Quarter

During the next quarter:

- Three implants will be done at HMRI for the purpose of studying bone and skin growth and to test the new cable design in vivo. Implant one is a split grooved Ti dummy plug with half the plug being stimulated electrically to encourage skin growth. Implant two is a split ceramic plug, half Alumna and half Zarconia. This will be placed on a normal Ti pedestal for osseointegration study. The third plug will

be grooved Ti with half the surface treated by UWEB (University of Washington Engineered Biomaterials) under an NSF grant with a laminin-5 "friendly" material to encourage Basal cell attachment. If it is not possible to use the UWEB treatment in this time frame it will be done later and another surface will be tried, probably one layer of sintered Ti beads similar to those used for osseointegration.

- The first dummy connectors using a CABAL-12 frit will be fabricated.
- A search for less exotic pin matrix or frit materials will continue in case CABAL-12 proves unsuitable.
- A method for attaching Silicone to Parylene will be developed and evaluated for use in the cable exiting the connector.
- Qualification of materials as Class VI will occur as materials are clearly identified.